

EXHIBIT A10

The Challenging Pelvic Examination

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While there is a large body of evidence on the effectiveness of Pap smears for cervical cancer screening and on screening for cervical gonorrhea and Chlamydia, there is sparse evidence to support other portions of the pelvic examination and little guidance on examination logistics. Maximizing comfort should be the goal; lubrication use and careful speculum selection and insertion can ease this intrusive procedure. This is particularly important in adolescent and menopausal women, sexual minorities, obese women, women with disabilities, and women with a history of trauma or prior instrumentation affecting the genitalia. We review the evidence and provide guidance to minimize physical and psychological discomfort with pelvic examination.

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Pelvic examinations are performed to evaluate pain, bleeding, and vaginal discharge and to screen for cervical cancer and sexually transmitted infections. Little attention has focused on the mechanics of pelvic examination technique, yet the examination is an intrusive experience for many women who feel exposed and lack control.¹ Emotional distress and fear of pain are cited as reasons for reduced adherence to cervical screening especially among adolescents,² racial/ethnic^{3–5} and sexual minority groups,⁶ obese women,⁷ victims of sexual assault and other trauma,⁸ and women with disabilities.⁹ Therefore, examination should be limited to components with proven utility and should be performed with cultural sensitivity and procedural excellence, especially in clinical situations that require particular finesse. Accordingly, we review the clinical evidence as it exists, and in areas that lack evidence offer our own experience to optimize technical aspects of speculum choice and insertion, and suggest strategies to manage challenging circumstances. When recommendations are not referenced, we are relating our experience in the absence of evidence.

COMPONENTS OF THE FEMALE PELVIC EXAMINATION

Few guidelines address visual inspection and bimanual examination. The United States Preventative Services Task Force

provides guidance only on Pap smear recommendations and absence of benefit of ovarian cancer screening.^{10,11} The American College of Obstetrics and Gynecology (ACOG) states that “... annual gynecologic examinations may still be appropriate even if cervical cytology is not performed at each visit,” but offers no evidence to support this recommendation or guidance on specific components of annual examinations.¹² The American Cancer Society (ACS) suggests that pelvic examinations may facilitate detection of non-cervical pelvic malignancies and gynecologic conditions,¹³ but does not specify what components comprise an annual pelvic examination nor cite evidence.

Bimanual examination is not useful as a screening test for ovarian cancer because of limited sensitivity and specificity. In one study, ovaries were palpable in 55% of women under 200 lbs during examination under anesthesia, but in only 9% of women over 200 lbs.¹⁴ In another study under similar circumstances, uterine size and contour were correctly assessed in over 50% of patients; however, sensitivity of examination for adnexal masses of 5 cm or greater was only 28% among attending gynecologists and 16% among gynecology residents.¹⁵ The USPSTF acknowledges poor performance characteristics of the bimanual examination in its recommendation about screening for ovarian cancer.¹¹ In the non-screening setting, bimanual examination is inadequate to evaluate acute abdominal pain or vaginal bleeding,¹⁶ since ultrasound is so much more sensitive and specific.

The most evidence-based approach would therefore suggest Pap smear collection alone and the speculum examination required to achieve that goal. We suggest that bimanual and sometimes rectovaginal examinations may be important in evaluating pelvic symptoms but are not required for routine screening. We suggest that other components of the pelvic examination need not be done.

PATIENT EDUCATION AND EMPOWERMENT

Many women feel anxious about pelvic examinations,¹⁷ especially if it is their first examination, they have had a prior negative experience, or there is a history of trauma.^{8,18} For such patients, we explain the rationale for the exam¹⁹ and encourage examination of the speculum, though there is no evidence that handling the equipment eases anxiety. Pelvic models and web-based images can enhance understanding of pelvic anatomy. When patients describe a prior negative experience, we gently elicit specific details and strategize together to minimize discomfort. Patient education is done before the patient reclines on the examination table and optimally while she is still clothed.

The presence of a chaperone is believed to enhance patient comfort, provide technical assistance, and ensure legal protec-

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tion. However, there are no universal guidelines regarding chaperone use, and there is no evidence that chaperones do reduce the likelihood of litigation. Policies in the US are ambiguous.²⁰ A 1997 review found that only 47% of state medical boards provided recommendations on this practice.²¹ In the United Kingdom, chaperones are required for pelvic examinations done by male providers, whereas female providers are required to ascertain patient preference in every examination.^{22,23} A study of 1,000 women at a Scottish family planning clinic found that the majority of patients prefer a chaperone with male examiners but not with female examiners.²⁴ In a small study of emergency room patients, 47% of female patients preferred a chaperone when examined by a man as compared to 26% when examined by a woman.²⁵ We therefore recommend routine use of chaperones by male clinicians, while female clinicians may wish to offer the presence of a chaperone and accommodate individual patients' preferences.

EXAMINATION ETIQUETTE AND COMMUNICATION

Language and technique should avoid sexual innuendo and maximize patient control and comfort. Positioning on the table should be accomplished with verbal cues and need only include physical contact if patients request assistance. We dislike the common practice of indicating optimal positioning by contact with the examiners hand at the end of the table and instead provide a verbal signal ("move down to the end of the table"). To respect modesty and maintain warmth, torso and legs are kept draped. We alert patients of examiner and instrument touch before they occur. Many women, especially adolescents, worry that their genitalia are abnormal. We therefore reassure with normal findings throughout the exam and inform the patient that cytology sampling may cause cervical bleeding and therefore short-term spotting.

VOIDING PRIOR TO EXAMINATION

We ask patients to void prior to examination as a full bladder causes discomfort during bimanual pressure, interferes with palpation of structures, and pulls the uterus superiorly, therefore making cervical localization more difficult. In older women with loss of pelvic floor tone, this maneuver reduces the chance of urinary leakage during digital or speculum insertion.

PATIENT POSITION AND STIRRUP USE

While the lithotomy position provides good visibility of the vulva and easy examiner access to the vagina, some patients experience it as disempowering, abusive, and humiliating.²⁶ Patients describe metal stirrups as "cold" and "hard," and experience their use as impersonal, sterile, or degrading.²⁷ Stirrups can be padded, and there are alternative foot supports.²⁷ A "no-stirrups" method, in which the patient is examined supine with the heel of each foot resting on a corner of the table, is used more commonly by clinicians in the UK, Australia, and New Zealand. A randomized controlled trial of 197 adult women undergoing routine cervical cancer screening documented reduced vulnerability and less discomfort using this method.²⁸ There were no significant differences in the

quality of Pap smears obtained, though the study was not powered to ensure adequacy of samples.²⁹ Alternative positions (see <http://www.bhawd.org/sitefiles/TblMrs/cover.html> for photos) include the V position (supine, hips abducted, knees extended); the M position (supine, hips abducted, knees flexed, feet at edges of table); the diamond position (supine, hips abducted, knees flexed, soles of feet touching); and the lateral position (lying on one side, hips and knees flexed).^{30,31} These modifications may be especially useful for patients with limited hip abduction or other musculoskeletal disabilities. We continue to use stirrups in most circumstances, but are flexible in trying other alternatives when the clinical situation warrants.

INSPECTION

Visual inspection of the external genitalia can reveal vulvar pathologies such as psoriasis, vulvar vestibulitis, condyloma, or neoplasia. We could find no evidence on the sensitivity or specificity of the external examination for any of these lesions and suggest a complete but brief inspection. Internal inspection might reveal cervical polyps, advanced cervical cancer, cervicitis, vaginal discharge, or vaginal wall erythema. There is no evidence that inspection increases detection of sexually transmitted infections.

LUBRICANT USE

Bacteriostatic, water-based gel is often omitted during speculum insertion for fear that it might interfere with cervical cytology and microbiology results.³² However, several studies have shown that water-based gel on either the outer, inferior bill of the speculum^{32,33} or on the vaginal introitus in addition to the speculum,³⁴ or on distal superior and inferior bills of the speculum³³ does not affect cervical cytology specimens. Lubricants containing "carbomers" or "carbopol polymers" may interfere with liquid prep Paps³⁵ and should be avoided. Studies have shown no decrease in endocervical detection rates of *Chlamydia trachomatis*³³ or group B streptococcus³⁶ among patients assigned to gel as opposed to water lubricant. Furthermore, growth of *Neisseria gonorrhoeae* was not inhibited following emulsification in water-based gel at any concentration.³⁷ Therefore, we and others recommend use of water-based gel during speculum insertion.³⁸ If bimanual examination is done first, the resultant well-lubricated vaginal introitus will reduce the risk of pain during subsequent speculum insertion. We suggest a dime-sized amount of lubricant deposited largely at the introitus; the amount of lubricant remaining on examining fingers for digital cervical contact should be similar to that contacting the cervix after speculum insertion through a lubricated introitus.

SPECULUM SELECTION

There are no references guiding examiners in their choice of speculum size. Anterior and posterior vaginal length, vaginal width, and introital measurements vary significantly, depending on race/ethnicity, age, parity, and height.^{39,40} Linear vaginal length ranges from 41–95 mm measuring from the

introitus at the level of the hymenal ring to the external cervical os. The vaginal fornix averages 42 mm, and the transverse vagina at 1 cm from the introitus averages 26 mm. In addition to these normal variations, vulvovaginal anatomy and physiology may be altered in a number of clinical circumstances such that tolerability and ease of speculum examination are impacted significantly. These include episiotomy, perineal lacerations, vulvar vestibulitis and vulvodynia, vaginismus, uterine or vaginal prolapse, fistulae, pelvic malignancy, a history of pelvic radiation, and female genital circumcision. An appropriately sized speculum should be chosen to accommodate individual anatomical features.

There are no set industry standards for speculae size, and manufacturers vary in their categorization. As a general principle, the wider the speculum, the greater the potential for patient discomfort in speculum insertion and opening, whereas the narrower the speculum, the more limited the visualization. We try to select the smallest speculum that permits optimal visualization. A Pederson medium has dimensions of 10 cm length and 2.5 cm width, and accommodates many patients acceptably. Traditional pediatric speculae are substantially shorter than other speculae and confer an advantage only when the cervix is <8 cm from the introitus. Ultra-narrow speculae, such as the Pederson specula extra narrow of 1.5 cm in width and 11.5 cm in length, are preferred for women with a narrow introitus due to postmenopausal atrophy, prior surgery or radiation, absent prior penile or sex toy vaginal insertion, or who simply experience discomfort during digital bimanual examination. Women with a micro-perforate or septate hymen who require vaginal inspection should be examined with extra-narrow speculae and referred to a gynecologist.

Speculae up to 4 cm wide and 12–16 cm long are appropriate when redundant vaginal walls prolapse between the bills and obscure the view of the cervix; this occurs most commonly in obese and multiparous women. If a larger speculum is ineffective in retracting vaginal walls, a condom can be rolled onto the speculum with the tip cut off, so that the sheath covering the space between the bills provides retraction. The longest possible speculum, Graves supersize XL with an 18-cm-long bill will be needed for women with an especially long vaginal vault when the cervix is barely reachable by the examining fingers.

We believe that the choice of metal versus plastic specula relates primarily to provider familiarity and opinion; there are no studies comparing patient comfort. Plastic speculae allow direct connections to lamps; their transparent bills also facilitate visualization. The audible and sensible clicks in locking plastic speculae position can be distressing, but one can avoid this by lifting the lock with one's thumb. From an environmental perspective, the argument for metal versus plastic resembles the debate between cloth versus disposable diapers; we have not seen an analysis comparing the landfill impact of plastic versus the resources required to sterilize and reuse metal speculae. Some speculum sizes and shapes are available only in metal, so providers using plastic should also have a few metal speculae with these characteristics.

SPECULUM INSERTION AND REMOVAL

Several resources provide a pictorial review of the mechanics of vaginal speculum insertion.^{41–43} The speculum should be

checked before use to be sure that the locking knobs (metal speculum) and click mechanism (plastic speculum) function correctly. Before inserting the speculum, pubic hair and labia must be fully retracted to provide adequate visualization and prevent entrainment of hair or tissue between the bills. Throughout the examination, the examiner should avoid the sensitive anterior structures (urethra, clitoris). During insertion, a gentle downward pressure of the speculum against the rectovaginal septum can ease opening of the vaginal vault. The speculum should be fully inserted to the hub before it is opened; the bills should then be opened slowly, and only as far as is necessary to clearly visualize the cervix. After specimen collection, the speculum should be closed loosely so that the vaginal walls and cervix are not pinched during removal.

Sometimes the cervix is not readily apparent when the speculum is first opened. When the cervix is not easily visualized, we recommend a bimanual examination to determine cervical location. If the cervix is deep in the vaginal vault and almost beyond reach of the examiner's fingers, a longer speculum will be needed. When there is significant uterine flexion, the cervix is located anteriorly; in this case, the speculum should be closed partially, retracted slightly, and redirected toward a more anterior location. If the uterus is acutely retroverted, the cervix may be lodged behind the symphysis pubis. In that case, exerting pressure on the posterior vaginal fornix may manipulate it into view.

SPECIAL POPULATIONS

Pelvic examination can be especially challenging with particular populations of women, requiring particular sensitivity and skill. We review each of these situations below.

ATROPHIC VAGINITIS AND VAGINAL STENOSIS

Speculum and digital examination can become painful in postmenopausal women with vulvovaginal atrophy. Vaginal atrophy, shortening, and stenosis with reduced elasticity are also common sequelae of pelvic irradiation.⁴⁴ In these settings, we suggest liberal use of lubricant and an ultra-narrow speculum; when insufficient, topical lidocaine application may be helpful. Topical lidocaine has not been studied in speculum insertion or bimanual examination, though it does reduce discomfort during laser vaporization of genital warts⁴⁵ and urethral catheterization.⁴⁶ While intravaginal estrogen cream or suppository has not been studied as a method to reduce pelvic examination discomfort, it has been shown to improve symptoms and findings of atrophic vaginitis⁴⁷ and in our experience can reduce discomfort during speculum insertion when used 2 weeks in advance of the examination. In any of these situations, graded vaginal dilators to stretch the vaginal introitus and vault can be advocated for women who are uncomfortable or no longer able to participate in penetrative sexual activities and wish to regain this capacity.

VULVODYNIA/VESTIBULITIS AND VAGINISMUS

Tactile discomfort with manipulation of the labia or the vestibule (the area surrounding the vaginal introitus) may be

due to vulvodynia/vestibulitis. Generous use of lubricant or lidocaine can be very helpful. Discomfort with digital or speculum insertion is often due to vaginismus—painful spasm of the muscles in the outer third of the vagina. This spasm may occlude the vagina, making internal examination impossible. The examination should be promptly discontinued, with reassurance that steps can be taken to try again another day. Since a history of trauma is common in patients with vaginismus,⁴⁸ management should proceed as if this were the case (see discussion below). Other interventions that may be useful to treat vaginismus include pelvic floor physical therapy, self-insertion of graded vaginal dilators, and cognitive behavioral therapy.⁴⁹

SEXUAL TRAUMA OR PHYSICAL ABUSE

Women who have experienced physical or sexual trauma are often particularly uncomfortable with pelvic examination.⁵⁰ Speculum or digital insertion may reawaken memories and

flashbacks, and may trigger anxiety and insomnia before, during, and after examination.⁵¹ Post-traumatic stress disorder in women with trauma may increase the likelihood of anxiety.⁵² While few women disclose a history of sexual trauma spontaneously,⁵³ a survey of women with a history of sexual abuse suggests that the majority favor routine inquiry.⁵⁴ Therefore, we suggest that all women, and especially those who have not had regular pelvic examinations or appear particularly uncomfortable, should be asked about a history of prior trauma. Preferably, this information should be elicited during the initial interview with the patient fully clothed or at least obtained before starting the examination, with the patient in a seated rather than supine position. The text box lists specific recommendations to ease performance of pelvic examinations in women with a history of trauma. This approach is also useful with patients who do not have a history of trauma per se, but who are apprehensive because of a previous difficult pelvic examination or a history of past perineal instrumentation, such as a voiding cystourethrogram in childhood.

Recommendations for examination in a woman who has experienced trauma

1. Offer the option of mental health counseling
2. Acknowledge that pelvic examinations may be difficult and normalize her anxiety
3. Accommodate requests such as preference for a female examiner as anxiety may be higher with male examiner (56)
4. Offer to have consultation only at the first visit unless she chooses to undergo the examination the same day
5. Offer to have a friend, family member, partner, or treater of the patient's choice present in the examination room; patients can also bring a comfort object such as a stuffed animal.
6. Offer the option to wear a dress or skirt and remove only the underwear for the examination
7. Assure her that if she decides to proceed, she will be able to stop the examination at any time
8. Negotiate what will happen if she asks to stop the examination (see text)
9. Offer positioning alternatives to the dorsal lithotomy position
10. Offer alternatives to speculum insertion including guided self insertion or insertion by a partner (57)
11. With patient's signed consent and a chaperone present, an anxiolytic medication may be taken prior to the examination in rare circumstances.

Patients with a history of trauma may dissociate during the examination,⁴⁸ becoming psychologically removed from the situation and reliving some aspect of the trauma. A patient's voice may revert to a childlike voice, or she may exhibit a startle response to ambient sounds. If this occurs, stop the exam and repeatedly reorient her to the present. We offer to discuss events with mental health providers with the patient's consent; we offer referral if she is not receiving mental health care.

SEXUAL AND GENDER MINORITY PATIENTS

Technically, pelvic examination is no more challenging in sexual minority women than in heterosexual women. However, creation of a safe and welcoming environment is of paramount importance when working with these populations, as many lesbian and bisexual women and transgender individuals are reluctant to undergo screening for cervical cancer and sexually transmitted diseases because of previous negative clinical experiences.⁵⁶ Due to gender dysphoria (preoperative patients) and concern regarding voyeurism on the part of health professionals (postoperative patients), many transgender individuals are particularly reticent to undergo genital examination.⁵⁷ Therefore, a solid alliance over a series of visits is often necessary before a pelvic examination is permitted. As with all other patients, the decision to perform a pelvic examination should be based on behavioral risk factors and reproductive organs present. A growing number of resources exist to guide appropriate care.⁵⁷⁻⁶⁰

WOMEN WITH DISABILITIES

Pelvic examination in women with cognitive, sensory, or mobility impairments can be challenging, but is important to perform. The National Study of Women with Physical Disabilities found that 94% of respondents were sexually active with sexually transmitted infection rates the same as in women with no disability.⁶¹ Several excellent resources have developed materials to enhance clinician sensitivity regarding the experience of having a disability and provide general guidance with respect to scheduling a realistic gynecological appointment length, installing appropriate office equipment, learning safe transfer techniques, and maintaining respectful etiquette when working with patients who present with a service animal, personal care assistant, or sign language interpreter.^{62,63}

For a woman with visual impairment, we offer the opportunity to feel the speculum and articulate each step of the exam before proceeding. For a deaf woman who wants her sign language interpreter to remain in the room, we negotiate where the interpreter will stand, so the patient can continue to communicate readily, yet the clinician can maneuver without hindrance. When personal care assistants are needed to help with transfers and position changes, patients should also meet alone with the clinician to ensure privacy for discussion of intimate topics, such as contraception, safer sex, and interpersonal violence. There is a high prevalence of abuse in women with disabilities, and both partners and assistants are often perpetrators.⁶⁴ Adaptive equipment, such as hydraulic stirrups, can be

used to facilitate examination in the lithotomy position. For a woman who cannot flex her knees, abduct her hips, or use stirrups for another reason, alternative positions can be attempted.^{30,31}

Most women with intellectual impairment are able to assent to and cooperate during pelvic examination when the procedure is carefully explained.⁶⁵ When this is not the case, sedation may be necessary; limited data suggest that this can often be accomplished without general anesthesia.⁶⁶ The ethics of this practice must always be carefully considered.⁶⁷

Particular care is also needed during pelvic examination in women with spinal cord injuries at or above T5-6, in whom perineal manipulation can cause unopposed stimulation of splanchnic nerves due to lack of central inhibition. This can result in autonomic dysreflexia: sympathetic output below the level of the lesion results in hypertension, while compensatory parasympathetic output above the level of the lesion results in nausea, headache, nasal congestion, flushing, sweating, and muscle spasms.⁶⁸ Prevention requires proactive management of the urologic and gastrointestinal tracts, including emptying the bladder prior to examination and maintaining an effective bowel regimen. Treatment of autonomic dysreflexia, when it occurs, requires immediate cessation of the exam, repositioning the patient in a more upright posture, loosening clothing, bladder catheterization to remove urine, checking for fecal impaction using lidocaine jelly, and short-acting antihypertensives, such as nitrates, if hypertension is severe and does not resolve promptly. Use of beta blockers should be avoided.

FEMALE GENITAL CIRCUMCISION

Although female genital circumcision is illegal in the United States, this practice continues worldwide. Circumcised women may become demoralized if examined by providers who are uninformed or alarmed by their genital appearance; cultural awareness and sensitivity are crucial. Several excellent reviews provide information about the range of procedures and resulting anatomical findings, cultural rationale and the potential medical complications.⁶⁹⁻⁷² Pelvic examination in a woman who has undergone infibulation (clitoridectomy, excision of the labia minora, and partial excision and reapproximation of the labia majora) may be impossible due to the narrowed introitus, scarring with introital/vaginal stenosis, and/or frequent occurrence of vaginismus requiring referral to a gynecologist with this particular expertise for examination and to discuss potential benefits of deinfibulation.

CONCLUSIONS

Pelvic examination can be a dual challenge for both clinicians and patients. We therefore endeavored to provide not only an evidence-based assessment of each component of the pelvic examination, but also recommendations to improve both the technical skill of clinicians and the acceptance and comfort of diverse populations of patients. With gentle persuasion, close collaboration with the patient, and a modicum of technical

creativity, even the most challenging pelvic examination can eventually be successful.

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